Safety and Security

iGEM is all about the use of synthetic biology in a social responsible way and biosafety issues are an important aspect of the competition therefore. In 2011, an extensive research is done into how the iGEM teams have quantitatively and qualitatively dealt with new safety requirements in recent years(Guan, Schmidt, Pei, Wei, & Ma, 2013). They found an increase in the number of teams reporting safety aspects and a general improvement in the safety assessment of their projects. Although the student's safety awareness has improved, certain gaps must still be filled before iGEM can fully live up to its role as an educational competition.

They have noticed that at that moment the safety-relevant characteristics of the registered parts were inadequate. Therefore, one of the suggestions they have made was to start with a mandatory safety evaluation for the biological parts in the Registry, which would provide future users with substantial safety documentation. Another point of interest was the fact that safety issues go beyond single parts to encompass higher-order constructs. This includes descriptions of the context dependency of parts in devices or systems, which are completely lacking from the Registry. Therefore, in their opinion more research has to be done into the safety issues of total constructs and final products.

In subsequent years, there were no major changes in the safety and security policy of iGEM. In our opinion, iGEM could play a much more important role in the general development of safety and security of synthetic biology. To improve the safety of our project, we have talked to safety experts of the TU Delft, who are specialized in risk analysis. They told us that one of the main problems of the risk- and safety analysis about synthetic biology is the fact that there is a lack of statistical data. For example, there is much more data available about the chemical industry or about the chance of a dike burst. We think that iGEM should take the lead in the data collection about synthetic biology. There are multiple ways to do this. First of all, in our opinion it would be wise to consider the introduction of a specific track about biosafety. In that case, teams participating in this track work to create more general knowledge about the safety of synthetic biology. For example, they could do research into biosafety issues of specific constructs or into the real impact of horizontal gene transfer. Another, in our opinion, interesting possibility could be to start a project, like Interlab, about biosafety. In this way, iGEM could start a large-scale and multi-annual project to collected the required data about biosafety and could therefore play a key role in the development of synthetic biology.

We also researched how safety is respected in other areas and fields. It appears that in many areas the analysis of possible safety issues is done in a more systematic way. For example, in aerospace engineering they have protocols to analyze risks and safety of many different types of events. We would propose to introduce more systematics in the analysis of risks of synthetic biology as well. Risk matrices are probably one of the most widespread tools for risk evaluation. They are mainly used to determine the size of a risk and whether or not the risk is sufficiently controlled (Figure 1).

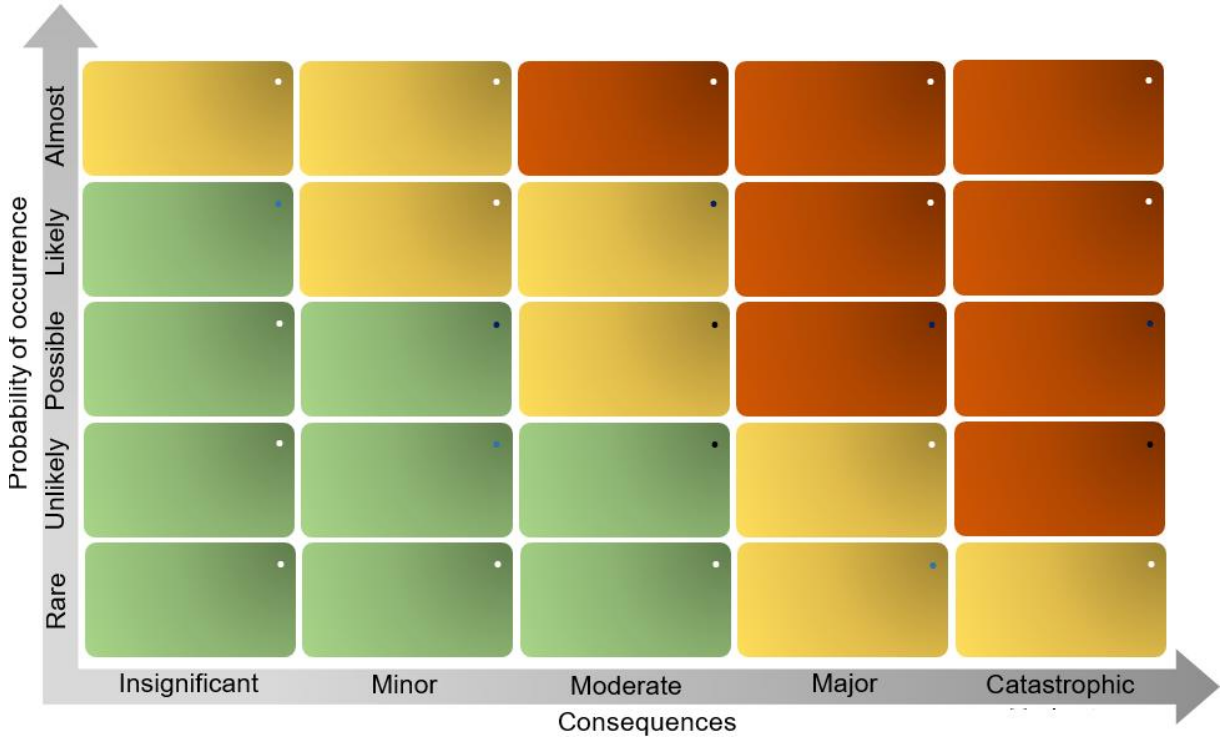

Figure 1. Risk Matrix

A risk matrix has two dimensions, respectively probability of occurrence/likelihood and impact. It looks at how large the impact is of a specific event and how likely it is that it will happen. These two dimensions create a matrix. The combination of probability and impact will give any event a place on a risk matrix.

Impact

There are multiple ways of looking at impact. In most cases the impact is judged from one of the four perspectives from the acronym PEAR: People, Environment, Assets and Reputation. Any event can be judged against these four categories. For instance: the explosion of a barrel with chemicals will firstly have a high impact on the contributors. The chemicals might have an impact on the environment and also the reputation of the organization that owns the barrel could be damaged. Furthermore, it could also have an impact on the asset of the organization.

Probability

The probability tells you how often a specific event theoretical will happen. For example, the probability of the explosion of a barrel with chemicals during the year is 0.01. This means that every 100 years a barrel will explode.

Sometimes it is difficult to determine what the probability of occurrence is. In many areas they look at the past and scores higher if the event has occurred more. However, as described before, there is not always enough data available about synthetic biology.

For the situation where there is a lack of data, expert judgment could provide an alternative. Expert judgment implies that the opinions of one expert or a group of experts is/are used to find a solution to a specific question. Their response is based on experience or knowledge or both.

One widely used technique for expert judgment is the so-called Delphi method. The technique is designed as a group communication process, which aims to achieve a convergence of opinion on a specific real-world issue. For the Delphi method a team of carefully chosen experts is required. In the first round, the experts will answer questions about the subject of interest. All the answers of the experts will be fed back anonymously. The experts have to take the opinions of the other experts into account and in this way they are encouraged to adjust their opinion. After this, a second comparable round with questions and feedback will start. Eventually this becomes an iterative process with multiple question and feedback rounds. The idea of this process is that the answers of the experts become more comparable every round and eventually the ultimate goal is to converge to one right answer(Linstone & Turoff, 1975). We would strongly recommend other iGEM teams to use this type of method to help you with analyzing the project.

As mentioned before, in our opinion the risk matrix is a very useful method to analyze risk issues of a project. Therefore, we have developed a hands-on safety application that can be used by iGEM teams to analyze the safety issues of their project. In this application aspects such as the used chemicals, types of used microorganism, etc. will be taken into account. The teams can use the tool to get in a more systematic and a visible insight into the risk issues of their project.